

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)  
August 15, 2012

DP BARCODE: 401807

MRID : 488019-01

SUBJECT: Antimicrobial Cupron Enhanced EOS Surface  
(Name of Product)

FILE SYMBOL: 84542-T

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [x]

INGREDIENTS:

| <u>PC Code(s)</u> | <u>CAS Number</u> | <u>Active Ingredient(s)</u> |
|-------------------|-------------------|-----------------------------|
| 025601            | 1317-39-1         | Cuprous oxide               |

TEST LAB: NA

SUBMITTER: Cupron Enhanced EOS Surface (Grey and Beige)

GUIDELINE: Product Chemistry Groups A and B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

DATE APPROVED: August 15, 2012

COMMENT:

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MEMORANDUM

SUBJECT: Product Chemistry Review for EPA File Symbol. 84542-T  
Product Name: Antimicrobial Curpon Enhanced EOS Surface  
DP Barcode: 401807

CODE: (A540) New Product; Non-Fast Track

DATE DUE: September 11, 2012

FROM: Earl Goad, Biologist  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510P)

TO: Jacqueline Campbell PM#34/Stacey Grigsby  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Applicant: Cupron, Inc.

PRODUCT FORMULATION FROM LABEL:

|                              |                 |
|------------------------------|-----------------|
| <u>Active Ingredient(s):</u> | <u>% by wt.</u> |
| Cuprous oxide                | 16.0            |
| <u>Other Ingredient(s):</u>  | <u>84.0</u>     |
| Total:                       | 100.0           |

## BACKGROUND:

Ag-Chem Consulting on behalf of Cupron Inc. has submitted an application for the new product registration of "Antimicrobial Cupron Enhanced EOS Surface" which has been assigned EPA File Symbol: 84542-T. This product is a polymeric material incorporated with Cuprous oxide which is used to form an antimicrobial covering to numerous articles. The product is formulated from an EPA registered source of the active ingredient.

The data package consists of:

1. A letter from the registrant dated April 15, 2012. This letter was found to require corrections to the name of the active ingredient. A corrected letter was received dated August 7, 2012.
2. Confidential Statements of Formula for Basic and Alternate formulations dated April 15, 2012. These CSFs also required corrections to the name of the active ingredient.
3. Product Label dated April 10, 2012.
4. Product Chemistry Study Document: MRID 488019-01 Brooks, M. (2012) Cupron Copper Enhanced EOS Surface, Product Chemistry, Group A: Product Identity, Composition and Analytical Test Guidelines and Group B: Physical and Chemical Properties Test Guidelines. Project Number: CUPRON40912. Unpublished study prepared by Ag-Chem Consulting. 21p.

## FINDINGS:

1. Confidential Statements of Formula: The corrected Basic and Alternate CSFs dated April 15, 2012 are acceptable.
2. Product label. The label is acceptable, except it is recommended that the equivalent % metallic copper in the product be stated immediately below the ingredient statement.
3. Product Chemistry Groups A and B. Please see Tables A and B for details.
  - a. Product Chemistry Group A data requirements have been satisfied.
  - b. Product Chemistry Group B data requirements have been satisfied.

## CONCLUSION:

The revised Basic and Alternate CSFs dated April 15, 2012 are found acceptable. It is recommended that the % metallic copper equivalent be stated below the ingredient statement on the product label.

## PRODUCT CHEMISTRY REVIEW

### I. CONFIDENTIAL STATEMENT OF FORMULA

#### a. Type of formulation and source registration:

- |  |         |        |
|--|---------|--------|
| • Non-integrated formulation system                      | Yes [X] | No [ ] |
| • Are all TGAIs used registered?                         | Yes [X] | No [ ] |
| • Integrated formulation system                          | Yes [ ] | No [X] |
| • If "ME-TOO," specify EPA Reg. No. of existing product: | NA      |        |

#### b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.

Yes [ ]      No [x]

*Note: This product is not intended for food use. All inert ingredients have PC codes. All formulation components are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated in April 2011 and available at [http://www.epa.gov/opprd001/inerts/inert\\_nonfooduse.pdf](http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf).*

#### c. Physical state of product:

*Solid*

#### d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X]      No [ ]

#### e. The NCs and CLs are acceptable.

Yes [X]      No [ ]

#### f. Active ingredients

|               | <u>NC</u> | <u>LCL</u> | <u>UCL</u> |
|---------------|-----------|------------|------------|
|               | (%)       | (%)        | (%)        |
| Cuprous oxide | 16.0      | 15.2       | 16.8       |

#### g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?  
Yes [ ]      No [ ]      Not applicable [X]
- Have all impurities of  $\geq 0.1\%$  in the product been identified?  
Yes [ ]      No [ ]      Not applicable [X]

## II PRODUCT LABEL

a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- |  |                              |  |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol:        | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level:           | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level:     | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form:                   | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

a. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.  
Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☒ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes ☒ No ☐

*Note: The active ingredient is measured as copper which is impregnated into polymeric material. It is reasonable to assume that in this form the copper will not change in form or chemical composition.*

**Table A:**  
**Product Chemistry (Series 830, Group A)**

| <b>Data Requirements</b>                            | <b>Acceptance of Information</b>   | <b>MRID No.</b>   |
|---|--|-------------------|
| 830.1550 Product Identity <sup>1</sup>              | A  | 48801901 and CSF  |
| 830.1600 Description of Materials                   | A – Materials are listed on CSFs – MSDS sheets were not provided.  | 48801901 and CSF  |
| 830.1620 Production Process <sup>2</sup>            | NA   |                   |
| 830.1650 Formulation Process <sup>3</sup>           | A  | 488019-01 and CSF |
| 830.1670 Formation of Impurities <sup>4</sup>       | A  | 488019-01         |
| 830.1700 Preliminary Analysis <sup>5</sup>          | <i>[Not required for products produced by a non-integrated system.]</i>  | 488019-01         |
| 830.1750 Certified Limits <sup>6</sup>              | A – EPA Standard certified limits were accepted.<br>A signed certification statement was provided, as requested under OPPTS 830.1750(g). | 488019-01 and CSF |
| 830.1800 Enforcement Analytical Method <sup>7</sup> | A – A copy of an ICP-MS method was provided for determining active ingredient content of the product.                                    | 488019-01         |
| 830.1900 Submittal of Samples                       | <i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>  |                   |

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

<sup>1</sup> See Confidential Appendix A for additional information.

<sup>2</sup> For MP/EP products produced by an integrated formulation system.

<sup>3</sup> For products from a TGA1 or MP.

<sup>4</sup> May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup> Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup> If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup> Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

**Table B:**  
**Physical and Chemical Characteristics (Series 830, Group B)**

| Physical/Chemical Properties*  | Acceptance of Data | Value or Qualitative Description   | MRID No.   |
|--|--------------------|--|------------|
| 830.6302 Color   | A                  | Grey or beige  | 488019-01  |
| 830.6303 Physical State  | A                  | Solid  | 488019-01  |
| 830.6304 Odor  | NA                 | Inodorous  | 488019-01  |
| 830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions | NR                 | [Not required for end-use products.]   |            |
| 830.6314 Oxidation/Reduction; Chemical Incompatibility                         | NA                 | The product does not contain an oxidizing or reducing agent.                       |            |
| 830.6315 Flammability/Flame Extension  | A                  | Not required EP product is solid   | 488019-01  |
| 830.6316 Explodability   | A                  | Not explosive.   | 488019-01  |
| 830.6317 Storage Stability   | A                  | Impregnated material   | 488019-01  |
| 830.6319 Miscibility <sup>1</sup>  | NA                 | Product is solid   | 488019-01  |
| 830.6320 Corrosion Characteristics   | A                  | Impregnated material   | 488019-01  |
| 830.6321 Dielectric Breakdown Voltage  | NA                 | NA -The end use product is not intended for use in or around electrical equipment. | 488019-01. |
| 830.7000 pH <sup>2</sup>   | NA                 | Product is solid   | 488019-01  |
| 830.7050 UV/Visible Absorption   | NR                 | [Not required for end-use products.]   |            |
| 830.7100 Viscosity   | A                  | Product is solid   | 488019-01  |
| 830.7200 Melting Point/Melting Range   | NR                 | [Not required for end-use products.]   | 488019-01  |
| 830.7220 Boiling Point/Boiling Range   | NR                 | [Not required for end-use products.]   | 488019-01  |
| 830.7300 Density/Relative Density/Bulk Density                                 | A                  | The density of the product was reported to be 2409.6 kg/m <sup>3</sup> .           | 488019-01  |
| 830.7370 Dissociation Constants in Water                                       | NR                 | [Not required for end-use products.]   | 488019-01  |
| 830.7550/830.7560/830.7570 Partition Coefficient                               | NR                 | [Not required for end-use products.]   | 488019-01  |
| 830.7840/830.7860 Water Solubility   | NR                 | [Not required for end-use products.]   | 488019-01  |
| 830.7950 Vapor Pressure  | NR                 | [Not required for end-use products.]   | 488019-01  |

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\* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

<sup>1</sup>If product is an emulsifiable liquid

<sup>2</sup>If product is dispersible with water